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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,264	07/08/2003	Yoichi Mikami	10793-005-999	8125

20583 7590 03/03/2006

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EXAMINER	
MARX, IRENE	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/615,264	MIKAMI ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/808448.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The application should be reviewed for errors.

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

The status of the parent case(s) should be updated.

Strain *B. stearothermophilus* JTS 859 has been deposited at National Institute of Biosciences and Human Technology of the Agency of Industrial Science and Technology under accession number FERM-BP- 6885 (Specification page 12). The deposit requirements are met in application serial No. 09/808448, now U.S. Patent No. 6,620,596(MPEP 2404.01).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2-5 and 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is vague and indefinite in the recitation of "as purine nucleoside phosphorylase and pyrimidine nucleoside phosphorylase, a microorganism itself which contains said enzymes or said enzymes derived from the microorganism are used". Amendment to --wherein the microbial purine nucleoside phosphorylase and pyrimidine nucleoside phosphorylase are contained in a microorganism or are obtained from a microorganism--, would be remedial, provided that claim 1 is amended to recite "microbial purine nucleoside phosphorylase and pyrimidine nucleoside phosphorylase".

Claims 4 and 5 are substantial duplicates.

Claims 1 and 6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed biotransformation with a microbial purine nucleoside phosphorylase and pyrimidine nucleoside phosphorylase, does not reasonably provide

enablement for the use of enzymes from other sources. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized in In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a prima facie case.

The breadth of the claims reads on a biotransformation procedure that can use an enzyme from any origin. Use of enzymes requires knowledge of a process for preparing them, knowledge of working conditions under which the enzyme retains activity and provision of any co-factors required by the enzymatic reaction in question. Thus, the conditions required for preparation and activity of a previously unknown enzyme are not *a priori* predictable.
As set forth in Ex parte Jackson, 217 U.S.P.Q. 804 (Bd. App. 1982)., the determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. The test is not merely quantitative, since a considerable amount of experimentation is permissible if it is merely routine or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed. Here, applicants' specification provides no guidance with respect to the selection or preparation of enzymes from a source other than a microorganism which would effect the claimed reaction. Moreover, Applicants rely on no reference indicating the state of the art with respect to this issue.

Accordingly, undue experimentation would be required to practice the claimed invention with respect to the selection and preparation of enzymes derived from sources other than microorganisms, particularly since a specific selection procedure, not described in the specification, would be required to avoid undue experimentation.

Thus, sound technical reasoning has been provided to support the conclusion that the limited guidance in the specification, considered in light of the relatively high degree of unpredictability in the particular art in question, would not have enabled one having ordinary skill in the art to practice the broad scope of the claimed invention without undue experimentation. In re Fischer 166 USPQ 18 (CCPA 1970)ydrolases would work in this instance.

Thus, the scope of the claims is not commensurate with the teachings of enablement of the specification.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Primary Examiner
Art Unit 1651